Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® for bone metastases.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Radiation Oncology-Bone Metastasis Work Group. Bone metastases. Reston (VA): American College of Radiology (ACR); 2003. 28 p. (ACR appropriateness criteria). [41 references]

GUIDELINE STATUS

This is the current release of the guideline.

It is a revision of a previously issued version (Bone metastases. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1077-104).

All Appropriateness Criteria™ are reviewed annually and updated as appropriate.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bone metastases

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Oncology
Radiation Oncology
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic procedures for treatment of bone metastases

TARGET POPULATION

Patients with bone metastases

INTERVENTIONS AND PRACTICES CONSIDERED

1. Surgery prior to radiation therapy
2. Radiation therapy:
    - Local radiation with 1–25 fractions
    - Hemibody irradiation
    - Strontium-89
    - Samarium
3. Complex blocking
4. Computer planning
5. Hormone therapy (e.g., stilphostrol)
6. Needle biopsy

MAJOR OUTCOMES CONSIDERED

- Quality of life
- Improvement in pain control
- Survival

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1–9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Bone Metastases

Variant 1: Patient with Karnofsky Performance Score (KPS) of 70. Diffuse, asymptomatic bone metastasis from a primary prostate cancer with prior orchiectomy. Has rising prostate specific antigen (PSA) and a new, asymptomatic bone metastasis at C3.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
600–800 cGy/1 fraction	2	
1200 cGy/2 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
2000 cGy/5 fractions	2	
3000 cGy/10 fractions	2	
3500 cGy/14 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Surgical intervention prior to radiation therapy (XRT)	2	
Computer planning	2	
Complex blocking	2	

Treatment	Appropriateness Rating	Comments
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 2: Patient with KPS of 70. Prostate cancer. No prior systemic treatment. Now has decreased deep tendon reflexes and early cord compression at T-10.

Treatment	Appropriateness Rating	Comments
Radiation therapy	9	Radiation shown to reverse early neurological deficits with high probability.
Local Radiation:		
3000 cGy/10 fractions	9	
2000 cGy/5 fractions	6	
3500 cGy/14 fractions	6	
600–800 cGy/1 fraction	3	
1200 cGy/2 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hormone Therapy	6	High dose stilphostrol used to reverse changes, but no controlled clinical trial.
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	No Consensus	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 3a: Patient with KPS of <40. Prostate cancer, prior orchiectomy. Received Strontium-89 two months ago. Has diffuse bone metastases and

pain but no neurological defect. Magnetic resonance imaging (MRI) reveals epidural metastases at T-4, T-9, and T-12.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
600–800 cGy/1 fraction	5	
1200 cGy/2 fractions	5	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial.
2000 cGy/5 fractions	5	
3000 cGy/10 fractions	3	
3500 cGy/14 fractions	3	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Radiation therapy	No Consensus	Panelists unable to decide whether patient without neurologic deficit should receive radiation therapy.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 3b: Patient with KPS of <40. Prostate cancer, prior orchiectomy. Received Strontium-89 two months ago. Previous bone scan 12 months ago showed diffuse metastases. Now with diffuse pain.

Treatment	Appropriateness Rating	Comments
Hemibody Irradiation:		
600–800 cGy/1 fraction	6	
Local Radiation:		
600–800 cGy/1 fraction	2	
1200 cGy/2 fractions	2	
2000 cGy/5 fractions	2	
3000 cGy/10 fractions	2	
3500 cGy/14 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Surgical intervention prior to radiation therapy	2	
Computer planning	2	
Complex blocking	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 4: Patient with KPS of 60. Recent diagnosis of large cell undifferentiated cancer of lung. Moderate back pain. Bone scan shows multiple metastases. Chest film discloses right upper lobe (RUL) and hilar masses. Plain film shows loss of L-4 pedicle.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
3000 cGy/10 fractions	8	
3500 cGy/14 fractions	8	For large volume
2000 cGy/5 fractions	6	
600–800 cGy/1 fraction	6	
1200 cGy/2 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Complex blocking	2	

Treatment	Appropriateness Rating	Comments
Computer planning	2	
Surgical intervention prior to radiation therapy	2	
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

<u>Variant 5a</u>: Patient with KPS <40. Prostate cancer. Received 3000 cGy to L4–L5 one year ago. Strontium-89 three months ago; now myelosuppressed. Recurrent back pain. Bone scan suggests reactivation of metastasis in lower lumbar spine.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
600–800 cGy/1 fraction	8	
1200 cGy/2 fractions	8	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial.
2000 cGy/10 fractions	8	No randomized studies and paucity of literature but panel voted that this fractionation program was safe over the estimated life-span of this patient.
3000 cGy/ 10 fractions	2	
3500 cGy/14 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Complex blocking	2	
Computer planning	2	
Surgical intervention prior to radiation	2	

Treatment	Appropriateness Rating	Comments
therapy		
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 5b: Patient with KPS of 60. Prostate cancer. One year ago, 3000 cGy to L4–L5. Strontium-89 three months ago. Recurrent back pain. Bone scan suggests reactivation of metastasis in lower lumbar spine. Complete blood count normal.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
600–800 cGy/1 fraction	8	
1200 cGy/ 2 fractions	8	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial.
2000 cGy/10 fractions	6	No randomized studies and paucity of literature but panel voted that this fractionation program was safe over the estimated life-span of this patient.
2000 cGy/ 5 fractions	3	
3000 cGy/10 fractions	3	
3500 cGy/14 fractions	2	
4000 cGy/ 20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Complex blocking	2	
Computer planning	2	
Surgical intervention prior to radiation therapy	2	
Radionuclides:		
Strontium-89: 4 mCi	No Consensus	Panelists could not agree on whether the patient was strontium-resistant.

Treatment	Appropriateness Rating	Comments
Samarium	No Consensus	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 5c: Patient with KPS of 60. Prostate cancer. Bone metastases in T-spine. Received 3000 cGy in 10 fractions to T-spine 1 year ago. Strontium-89 three months ago. Bone scan suggests reactivation of T-spine metastases in previously treated area. No pain.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
600–800 cGy/1 fraction	2	
1200 cGy/ 2 fractions	2	
2000 cGy/10 fractions	2	
3000 cGy/10 fractions	2	
3500 cGy/14 fractions	2	
4000 cGy/ 20 fractions	2	
5000 cGy/25 fractions	2	
2000 cGy/ 5 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Radiation therapy	2	Panelists unwilling to deliver additional radiation to T-spine in patient without pain.
Complex blocking	2	
Computer planning	2	
Surgical intervention prior to radiation therapy	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 5d: Patient with KPS of 60. Prostate cancer. Bone metastases in T-spine. Received 3000 cGy in 10 fractions to T-spine 1 year ago. Strontium-89 three months ago. Bone scan suggests reactivation of T-spine metastases in previously treated area. Patient has localized pain.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
2000 cGy/10 fractions	8	Despite a lack of literature, panelists endorsed re-irradiation to a low dose.
600–800 cGy/1 fraction	8	Panelists preferred 600 cGy because of the previous irradiation.
1200 cGy/ 2 fractions	2	Not recommended because of previous irradiation
2000 cGy/ 5 fractions	2	
3000 cGy/10 fractions	2	
3500 cGy/14 fractions	2	
4000 cGy/ 20 fractions	2	
5000 cGy/25 fractions	2	
Radionuclides:		
Strontium-89: 4 mCi	3	
Samarium	3	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Complex blocking	2	
Computer planning	2	
Surgical intervention prior to radiation therapy	2	Only consider surgical intervention if impending cord compression.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 5e: Patient with KPS of 60. Prostate cancer. Bone metastases in T-spine. Received 3000 cGy in 10 fractions to T-spine 1 year ago. Strontium-89 three months ago. Bone scan suggests reactivation of T-spine metastases in previously treated area. Patient has pain and spinal cord compression.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
2000 cGy/ 10 fractions	8	With or without surgical intervention

Treatment	Appropriateness Rating	Comments
600–800 cGy/1 fraction	7	Panelists preferred 600 cGy for only postoperative patients because of the previous irradiation.
1200 cGy/ 2 fractions	2	
2000 cGy/ 5 fractions	2	
3000 cGy/10 fractions	2	
3500 cGy/14 fractions	2	
4000 cGy/ 20 fractions	2	
5000 cGy/25 fractions	2	
Surgical intervention	7	Some panelists suggested hormonal manipulation was an appropriate alternative to this more invasive option.
Hemibody Irradiation:		
600-800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Complex blocking	2	
Computer planning	2	
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

<u>Variant 6</u>: Patient with KPS of 60. One-month history of adenocarcinoma of the lung, stage III-B. Received palliative radiation to the lung. Right femur pinned for 50% destruction of the cortex by metastatic disease. Now referred by orthopedist.

Treatment	Appropriateness Rating	Comments
Surgical intervention prior to radiation therapy	8	Literature endorses prophylactic fixation prior to radiation for >1/3 cortical thickness involvement.
Complex blocking	8	To include the proximal femur, acetabulum, and ischium with

Treatment	Appropriateness Rating	Comments
		exclusion of viscera.
Local Radiation:		
2000 cGy/ 5 fractions	8	
3750 cGy/15 fractions	8	
3000 cGy/10 fractions	8	
3500 cGy/14 fractions	8	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
1200 cGy/ 2 fractions	No Consensus	No experience or literature. Possible clinical trial.
600–800 cGy/1 fraction	No Consensus	No experience or literature. Possible clinical trial.
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Computer planning	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 7: Patient with KPS of 50. Renal cell carcinoma. Bone scan shows multiple metastatic lesions. Severe right hip pain when walking; none at rest. Plain film shows 3-cm lytic lesion involving more than one third of cortex of bone.

Treatment	Appropriateness Rating	Comments
Radiation therapy	9	
Complex blocking	8	To include the proximal femur, acetabulum, and ischium with exclusion of viscera.
Local Radiation:		
2000 cGy/5 fractions	8	
3000 cGy/10 fractions	8	

Treatment	Appropriateness Rating	Comments
3500 cGy/14 fractions	8	
3750 cGy/15 fractions	6	
1200 cGy/2 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
600–800 cGy/1 fraction	No Consensus	Too little experience with renal cell carcinoma.
Surgical intervention prior to radiation therapy	6	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Computer planning	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 8a: Patient with KPS of 80. Breast carcinoma, stage I, 15 months ago. Treated with 6 cycles of cyclophosphamide-methotrexate-5-fluoruracil (CMF). Now has low back pain. Bone scan and MRI show destructive lesion at L–4. No cord involvement. Biopsy shows breast cancer. Solitary lesion.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
2000 cGy/5 fractions	8	
3000 cGy/10 fractions	8	
3500 cGy/14 fractions	8	
1200 cGy/2 fractions	2	
5000 cGy/25 fractions	2	
4000 cGy/20 fractions	2	
600–800 cGy/1 fraction	No Consensus	Panelists were undecided because of the length of the disease-free interval.

Treatment	Appropriateness Rating	Comments
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Computer planning	No Consensus	For patient with a solitary lesion and a long natural history, more sophisticated treatment planning may be considered.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 8b: Patient with KPS of 80. Breast carcinoma, stage I. Treated with 6 cycles of CMF, 5 years ago. Now has low back pain. Bone scan and MRI show destructive lesion at L-4. No cord involvement. Biopsy shows breast cancer. Solitary lesion.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
3750 cGy/15 fractions	8	
3000 cGy/10 fractions	8	
3500 cGy/14 fractions	8	
2000 cGy/5 fractions	6	
4000 cGy/20 fractions	6	
5000 cGy/25 fractions	5	
1200 cGy/2 fractions	2	
600–800 cGy/1 fraction	No Consensus	Panelists were undecided because of the length of the disease-free interval.
Hemibody Irradiation:		

Treatment	Appropriateness Rating	Comments
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Computer planning	No Consensus	For patient with a solitary lesion and a long natural history, more sophisticated treatment planning may be considered.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 8c: Patient with KPS of 80. Malignant melanoma, excised 7 years ago. Now has low back pain and solitary metastasis at L-4, no cord involvement.

Treatment	Appropriateness Rating	Comments
Local Radiation:		
3000 cGy/10 fractions	8	
5000 cGy/25 fractions	8	
3000 cGy/5 fractions/2.5 weeks	6	
1200 cGy/2 fractions	2	
600-800 cGy/1 fraction	No Consensus	Panelists could not agree on the radiosensitivity of melanoma to this schedule. They differed on the tempo of future metastases.
2000 cGy/5 fractions	No Consensus	
3500 cGy/14 fractions	No Consensus	Many panelists (but not enough to achieve consensus) preferred high dose, protracted treatment schedules.
3750 cGy/15	No Consensus	

Treatment	Appropriateness Rating	Comments
fractions		
4000 cGy/20 fractions	No Consensus	
Needle biopsy	6	
Complex blocking	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Surgical intervention prior to radiation therapy	No Consensus	
Computer planning	No Consensus	For patient with a solitary lesion and a long natural history, a more sophisticated treatment planning may be considered.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 9a: Patient with KPS of 30. Breast cancer 3 years ago. Radiation therapy (XRT) to multiple bony sites. Refractory to hormones and chemotherapy. MRI shows destructive C-5 lesion. No prior XRT to C-5. Numb left arm and impending cord compression.

Treatment	Appropriateness Rating	Comments
Radiation therapy	6	
Local Radiation:		
2000 cGy/5 fractions	8	
600–800 cGy/1 fraction	6	
1200 cGy/2 fractions	6	
3000 cGy/10 fractions	6	
3500 cGy/14 fractions	6	For large volume
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	

Treatment	Appropriateness Rating	Comments
Samarium	2	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 9b: Patient with KPS of 70. Treated for breast cancer 3 years ago with adjuvant chemotherapy. No prior XRT. MRI shows evidence of impending cord compression at C-5 lesion. Physical exam shows slight increased arm and leg reflexes bilaterally. Bone scan is positive at low C-spine, T-spine, both sacroiliac (SI) joints. Pain C-spine only.

Treatment	Appropriateness Rating	Comments
Radiation therapy	8	Radiation therapy recommended for C-spine only
Local Radiation:		
3000 cGy/10 fractions	9	
3500 cGy/14 fractions	9	For large volume
2000 cGy/5 fractions	6	
600–800 cGy/1 fraction	3	
1200 cGy/2 fractions	2	
5000 cGy/25 fractions	2	
4000 cGy/20 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	Despite literature support for this approach, panel unwilling to support hemibody irradiation (HBI).
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Radionuclides:		

Treatment	Appropriateness Rating	Comments
Strontium-89: 4 mCi	2	
Samarium	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 9c: Patient with KPS of 70. Treated for malignant melanoma with multiple metastatic bone lesions. No prior XRT. MRI shows evidence of impending cord compression at C-5 lesion. Physical exam shows slight increased arm and leg reflexes bilaterally. Bone scan is positive at low C-spine, T-spine, both SI joints. Pain C-spine only.

Treatment	Appropriateness Rating	Comments
Radiation therapy	9	Radiation therapy recommended to C-spine only
Local Radiation:		
2000 cGy/5 fractions	7	
3000 cGy/10 fractions	7	
3500 cGy/14 fractions	7	
600–800 cGy/1 fraction	4	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
1200 cGy/2 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Computer planning	2	
Complex blocking	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Surgical intervention prior to radiation therapy	No Consensus	Individualization required
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 10a: Patient with KPS of 45. Breast cancer. Multiple bone metastases treated with radiation including T-spine. Prior chemotherapy

and hormones. Destructive rib lesions adjacent to T-spine, all encompassed in one radiation portal.

Treatment	Appropriateness Rating	Comments
Radiation therapy	8	
Local Radiation:		
600–800 cGy/1 fraction	8	
1200 cGy/2 fractions	8	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial
2000 cGy/5 fractions	6	
3000 cGy/10 fractions	5	
3500 cGy/14 fractions	5	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	6	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 10b: Patient with KPS of 45. Breast cancer. Multiple bone metastases treated with radiation including T-spine. Prior chemotherapy and hormones. Severe chest wall pain and destructive rib lesions adjacent to T-spine, all encompassed in one radiation portal.

Treatment	Appropriateness Rating	Comments

Treatment	Appropriateness Rating	Comments
Radiation therapy	8	
Local Radiation:		
600–800 cGy/1 fraction	8	
1200 cGy/2 fractions	8	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial
2000 cGy/5 fractions	6	
3000 cGy/10 fractions	4	
3500 cGy/14 fractions	4	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	6	
Computer planning	2	
Complex blocking	2	
Surgical Intervention Prior to Hemibody Irradiation		
600–800 cGy/1 fraction	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

<u>Variant 11a</u>: Patient with KPS of 60. Multiple myeloma. Metastatic survey shows punched out lesions in most bones including the lumbar spine. Just started on a course of Alkeran and Prednisone. Referred by medical oncologist for intractable low back pain.

Treatment	Appropriateness Rating	Comments
Radiation therapy	8	Delivered to L-spine only. Hemibody

Treatment	Appropriateness Rating	Comments
		irradiation as a primary approach is not recommended.
Local Radiation:		
3000 cGy/10 fractions	7	Successful palliation has been reported for lower doses.
3500 cGy/14 fractions	6	Successful palliation has been reported for lower doses.
1800 cGy/6 fractions	6	
2400 cGy/12 fractions	6	
3000 cGy/15 fractions	6	
600–800 cGy/1 fraction	6	
1200 cGy/2 fractions	6	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial
2000 cGy/5 fractions	6	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 11b: Patient with KPS of 60. Multiple myeloma. Metastatic survey shows punched out lesions in most bones including the lumbar spine. Chemotherapy for 8 months; failed melphalan (L-PAM)/Prednisone, and

vincristine-doxorubicin-dexamethasone (VAD). Referred for intractable low back pain.

Treatment	Appropriateness Rating	Comments
Radiation therapy	9	
Local Radiation:		
600–800 cGy/1 fraction	8	
2000 cGy/5 fractions	8	
1200 cGy/2 fractions	8	1200 cGy in 2 fractions one week apart was recommended if there was a response after 600 cGy. Possible clinical trial
1800 cGy/6 fractions	6	
2400 cGy/12 fractions	6	
3000 cGy/10 fractions	6	
3000 cGy/15 fractions	4	
3500 cGy/14 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 12: Patient with KPS of 60. Untreated small cell carcinoma of the lung and diffuse metastases involving sacrum, adjacent ilium, ischium, and femur. Referral for concomitant XRT with chemotherapy. Sacral, hip, and leg pain.

Treatment	Appropriateness Rating	Comments
Radiation therapy	6	Panelists believed that concomitant radiation therapy was probably appropriate and need not wait for response to chemotherapy.
Local Radiation:		
2000 cGy/5 fractions	5	
600–800 cGy/1 fraction	5	Choice of 600 cGy versus 800 cGy depends on volume.
3000 cGy/10 fractions	5	
3500 cGy/14 fractions	5	
1200 cGy/2 fractions	2	
4000 cGy/20 fractions	2	
5000 cGy/25 fractions	2	
Hemibody Irradiation:		
600–800 cGy/1 fraction	2	
Computer planning	2	
Complex blocking	2	
Surgical intervention prior to radiation therapy	2	
Radionuclides:		
Strontium-89: 4 mCi	2	
Samarium	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

In the United States, approximately one half of patients who receive radiation therapy are treated with palliative intent. The goals of palliation include the relief of symptoms, if present, or the prevention of symptoms that are likely to occur in the future, referred to as prophylactic or prospective palliation.

The Patterns of Care Study survey of palliative care found that weight-bearing and non–weight-bearing bones were the predominant sites for palliative therapy with the goals of treatment being relief of pain or return of function. The most commonly practiced schedule was 30 Gy in 10 daily fractions of 3 Gy each. Many weight-bearing bones received 40 Gy in 20 fractions, whereas some non–weight-bearing bones were treated with shorter courses of radiation. Both Hendrickson et al and Tong et al found that 90% of patients experienced some pain relief with radiotherapy and 50% had complete pain relief. Short-course, low-dose treatment schedules were as effective as more aggressive, protracted fractionation schemes. The Radiation Therapy Oncology Group (RTOG) data were reanalyzed by Blitzer who came to the opposite conclusion. Namely, that protracted dose fractionation schedules (40.5 Gy in 15 fractions and 30 Gy in 10 fractions) were more effective in terms of pain relief, need for narcotics, and freedom from retreatment, than short-course schedules (15 Gy in 5 fractions, 20 Gy in 5 fractions, or 25 Gy in 5 fractions). In a multivariate analysis, Gilbert et al demonstrated that neither primary site nor irradiation dose level determined pain relief or the quality of life. Allen et al reached a similar conclusion.

Retrospective and prospective studies from Europe have shown that 8 Gy in a single fraction provides pain relief similar to 30 Gy in 10 fractions. Hoskin et al randomized patients to receive 4 Gy or 8 Gy in single doses. Although the overall response rate was significantly higher in the 8 Gy group, the complete response rate, duration of response, and survival were similar for both doses. Cole randomized patients to 24 Gy in 6 fractions in two to three weeks and 8 Gy in a single fraction. Nausea was twice as frequent with 8 Gy as compared with 24 Gy (average field size of 150 cm^2). Although the response to radiotherapy was similar at both dose levels, 25% of patients in the single-dose group required retreatment. Deterioration in functional status was due to advancing cancer in other than the irradiated sites in both groups.

Other fractionation schedules have also been studied. Madsen found that pain control achieved with 24 Gy in 6 fractions over 21 days was identical to that observed with 20 Gy in two fractions over 8 days. Adding his prospective randomized data to a pertinent literature review, Madsen concluded that no optimal radiation schedule or dose exists for reducing pain from bone metastases.

Four randomized studies totaling more than 2000 patients have been published with one arm being a single fraction of 8 Gy x 1. The Danish Bone Metastasis study randomized between 8 Gy and 1 versus 4 Gy x 6. Questionnaires were used for follow-up, and median survival was 7 months. The Bone Pain Trial Working Party (United Kingdom) randomized 8 Gy x 1 versus 4 Gy x 5 or 3 Gy x 10. Questionnaires were used. Median survival was 11 months. A Danish study compared 8 Gy x 1 versus 5 Gy x 4. Questionnaires were alternated with follow-up visits. The median survival was 8.5 months.

One study evaluated multiple daily fractions for palliation of bone metastases. Okawa et al randomized patients with symptomatic metastatic bone tumors to 30 Gy in 10 fractions in 20 to 22 days, 22.5 Gy in 5 fractions in 14 to 16 days, and 20 Gy in 5 to 7 days, given at 2 Gy twice daily, three times per week. Pain control was identical in all three groups. The investigators concluded that radiotherapy schedules should be individualized on the basis of factors such as performance status, stage, site of metastases, and size of the radiation field.

From Edinburgh, 265 patients were randomized between 10 Gy x 1 and 4.5 Gy x 5. Patients were followed with questionnaires and follow-up visits. Median survival was approximately six months. In all the above studies, the single fraction was as successful as multiple fractions.

Elective irradiation for prospective palliation given to patients with asymptomatic metastatic bone tumors that may cause future catastrophic events, such as pathologic fractures of the femur, thoracic spinal cord compression, or severe pain abruptly altering the quality of life, has been delivered in various forms: external beam irradiation, wide-field regional irradiation, and systemic radionuclides. Radiation of uninvolved bones may delay or prevent the subsequent appearance of bone metastases. Bagshaw et al incidentally irradiated the lumbar spine while treating the paraaortic lymph nodes in patients with carcinoma of the prostate. For patients whose lumbar spines received 35 to 50 Gy in 2 Gy fractions, the actuarial five-year incidence of lumbar spine metastases was 50%, compared with 80% for those irradiated to the pelvis only. Further investigation might show a difference in spinal cord compression, but the number of patients in the trial would have to be much greater.

Poulter et al showed in a randomized trial that adding hemibody irradiation to standard fractionated radiotherapy (30 Gy in 10 fractions) decreased the time to disease progression, the time to new disease, and the time to new treatment by 10% to 15% in the targeted hemibody. Dearnaley et al in a matched pair analysis compared the palliative benefits of hemibody irradiation and strontium-89 in patients with metastatic prostate cancer. These treatments were found to be equally effective with respect to pain palliation and survival. Toxicities consisting of nausea and vomiting and the need for transfusions were more severe in the hemibody-irradiated group. Performance status and extent of disease were more important than the choice of management regimens in determining outcome.

The systematic control of carcinomatous bony pain has shifted from an interest in half-body irradiation to that of bisphosphonates and radionuclides. The bisphosphonates inhibit osteolysis by reducing osteoclast functions. Because bisphosphonates therapy acts on bone rather than tumor metabolism, any claim of increased survival is probably due to the concomitant chemotherapy. Bisphosphonates can reduce pain and hypercalcemia. This response can be determined after one to two weeks of weekly intravenous or daily oral treatment.

In an analysis of 751 patients, the proportion of patients developing skeletal-related events was 60% in the placebo group and 40% in the Pamidronate group at 30 months. Bisphosphonates therapy is expensive, must be continued indefinitely and does not abolish the risk of skeletal complications, but merely delays their onset. Targeting bisphosphonates to subgroups of patients such as those with solitary metastases has been suggested.

In a randomized study on patients with cancer of the prostate, Porter et al found that patients given strontium-89 (10.8 mCi) in addition to local field external beam irradiation (30 Gy in 10 fractions), had significantly improved pain control and a reduced requirement for further irradiation and analgesic medication for four months when compared with those treated only with local field irradiation. Bolger et al confirmed the finding that strontium-89 (5.4 mCi) is superior to local irradiation and hemibody irradiation in terms of reducing the rate of appearance of new sites of pain.

Phosphorus-32, strontium-89, and samarium-153 are radionuclides available for pain palliation from bony metastasis. A randomized study evaluating pain relief from phosphorous-32 versus strontium-89 showed no difference. The most popular radionuclide prescribed in the United States is strontium-89. The given dose of strontium varies, and the long half-life can result in radiation safety difficulties for patients who die in a few months. The life of strontium-89 is 50.5 days versus 47 hours for samarium-153. Both radionuclides are completely excreted in the urine within 48 to 96 hours. With regard to a urine spill, both radionuclides have almost the same hazards, millicurie for millicurie, except that samarium has a gamma ray component. However, with a high level of fixed contamination, samarium-153 is superior. With a samarium spill, the area would have to be isolated for 10 to 30 days, whereas strontium-89 it might be 356 days. The presence of a gamma emitter in strontium-85 has influenced Giammarile et al to evaluate its efficacy. Mean survival of 108 patients was approximately 10 months. Those patients with fewer metastases (bone scan) and a higher performance score did better. The mean dose to the metastasis was about 500 cGy; with a wide range there was no difference in estimated absorbed dose for nonresponders and responders. Treatment of strontium-89 in patients with endocrine-refractory prostate cancer has not lengthened survival. Some improvement in pain in 75% of patients lasting for 6 months is a benchmark treatment baseline for radionuclides. As in patients given bisphosphonates, selection of a subset of patients for radionuclide administration is not defined nor is it similar among reporting institutions. No studies to date have shown any difference in outcome for phosphorous-32, strontium-89, or samarium-153.

Few reports address the treatment of metastatic bone tumors arising from "radioresistant" primary sites. In one study, 45 Gy in 4.5 weeks was recommended for symptomatic metastatic lesions arising from renal cell carcinoma.

The quality of life of patients who undergo surgical fixation of metastases within long bones before the occurrence of fracture is considerably better than those with pathologic fractures. If lesions can be measured, those measuring 3 cm or destroying 50% of the cortex of tubular bone in a single radiograph should be considered for fixation before irradiation because of the tendency to fracture either during or shortly after treatment.

Delineation of the volume and anatomic location of the metastatic site for local field irradiation therapy is still lacking in most reports. Dawson et al have written a thoughtful criticism of our clinical practice of pain palliation by radiation. Studies in dose-time are still needed. The study of Jeremic et al of 300 patients has suggested that a single dose of less than 8 Gy x 1 is as effective as fractionated therapy. Maranzano et al have treated 53 patients with cord compression effectively by starting out with a single dose of 8 Gy (plus Dexamethasone) and repeating it one week later if there is no clinical progression. Median survival was 6 months.

Most cord compressions from vertebral metastases extending into the epidural space can be managed with high-dose corticosteroids and radiation. Surgery is indicated when vertebral body collapse causes mechanical impingement on the spinal cord or nerve roots, often associated with a history of progressive neurologic deficit over 72 hours or less. Surgery should also be considered if the diagnosis is in doubt, if stabilization is necessary, or if radiotherapy has already been given to the same area.

In summary, doses in the range of 20 Gy in 5 fractions to 30 Gy in 10 fractions or 35 to 37.5 Gy in 14 to 15 fractions in better-prognosis patients are acceptable in most circumstances. Complex blocking strategies and computerized planning are thought to be inappropriate. The expert panel did not attempt to examine the point of dose prescription. In the literature, dose is variously prescribed as a given dose, a dose at a depth (usually 5 cm), or a dose at midplane. [The panel hoped that future reports on the palliation of bone metastases would be explicit in the description of dose prescription points. Finally, the panel could not agree upon situations where prospective palliation was appropriate.]

Perspective

Although the RTOG over 10 years ago demonstrated that 20 Gy in 5 fractions gave similar results to more protracted regimens, most clinical trials investigating schedules with less than 10 fractions have been performed outside of the United States. Consequently, most radiation oncologists in the United States lack experience with daily doses of 4 Gy or more. To determine the optimal dose fractionation scheme, more emphasis should be placed on the life expectancy of the patient. A dose of 20 Gy in 5 fractions or even more rapid schedules is acceptable in patients with short life expectancy (i.e., less than three months). Unfortunately, there is little agreement or information on objective correlates to life expectancy. Thus, performance status was used as a surrogate for this measure by the panel. Based on these observations, at least two areas of research should be considered: 1) measurement of the efficacy of a 1- to 5-fraction course of palliation and 2) the definition of a group of patients with a very limited life expectancy, say three months, in whom a short course of palliative radiation might be considered. This research can best be done in a cooperative group setting, and the conclusions would represent an important contribution to issues related to health care cost containment.

Ratanatharathorn et al have critically reviewed the bone metastasis literature and provided explanations why members of the Bone Metastasis Work Group and other North American radiation oncologists have ignored the summarized literature support for hypofractionated approaches to pain palliation. The sites of the metastases in the published studies varied, making comparison between trials, a meta-analysis, impossible. The mix of patients with early versus late metastatic disease also varied. Median survival ranged from five to 12 months, making general statements about the need for retreatment and duration of response questionable. The American review commented about the heterogeneity of treatment technique and dose specification. It echoed the criticisms of the Dawson et al review with respect to both pain assessment scales, ability to evaluate patients at various time points post-treatment and control for other therapies.

Despite ample literature support for both hemibody irradiation and strontium-89 administration, the panelists were not enthusiastic about their use. The side effects and the need for hospitalization influenced the decision not to recommend hemibody irradiation. The addition of ondansetron and its analog to the antiemetic armamentarium suggest that trials with outpatient hemibody irradiation should be considered.

Most panelists had experience treating patients with strontium-89 and were uniformly disappointed with the degree of pain palliation, the durability of the response, or the cost-benefit ratio, given the high cost of this agent. It is thought that the disappointing results observed by the panel members may be related to issues regarding dosage. Porter et al used a dose of 10.8 mCi, whereas allowable dose in the United States is only 4 mCi. Alternatively, the poor responses might be due to adverse selection of patients with highly advanced disease. The panel suggested that other trials be undertaken with single or multiple 4 mCi doses to assess the efficacy of this agent at dose levels allowed by the Food and Drug Administration, using a documented pain scale for evidence of response.

Research is needed to define when prospective palliation should be undertaken and to establish the clinical indications for treatment with hemibody irradiation, strontium-89, and other unsealed nuclides. In addition, several panelists noted the lack of literature on the interaction of low energy supervoltage radiation with bedsores in the poor performance patient. They urged that methods of radiation delivery that avoid the exacerbation of decubitus ulcers be examined.

It is unlikely that studies on bisphosphonates and radionuclides will be reserved for patients who are refractory to chemotherapy or have too many lesions for local field radiation therapy. Already many investigators have shown a prejudice to use these systemic agents earlier in the course of disease or as a prevention measure. Unfortunately this will impede the initiation of studies that will help to establish which patients should qualify for these systemic treatments. To complicate matters even further is the hypothesis that earlier treatment with these agents will be more cost-effective, despite the initial higher cost.

Anticipated Exceptions

None

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate selection of radiologic treatments for bone metastases to palliate pain, reduces the need for analgesic medication, and reduces the number of new sites of pain

POTENTIAL HARMS

Toxicities of radiation therapy include:

- Nausea and vomiting
- Need for blood component transfusion

The most popular radionuclide prescribed in the United States is strontium-89. The given dose of strontium varies, and the long half-life can result in radiation safety difficulties for patients who die in a few months. The life of strontium-89 is 50.5 days versus 47 hours for samarium-153. Both radionuclides are completely excreted in the urine within 48 to 96 hours. With regard to a urine spill, both radionuclides have almost the same hazards, millicurie for millicurie, except that samarium has a gamma ray component. However, with a high level of fixed contamination, samarium-153 is superior. With a samarium spill, the area would have to be isolated for 10 to 30 days, whereas strontium-89 it might be 356 days.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Radiation Oncology-Bone Metastasis Work Group. Bone metastases. Reston (VA): American College of Radiology (ACR); 2003. 28 p. (ACR appropriateness criteria). [41 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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American College of Radiology - Medical Specialty Society

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GUIDELINE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Radiation Oncology-Bone Metastasis Work Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

It is a revision of a previously issued version (Bone metastases. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1077-104).

All Appropriateness Criteria™ are reviewed annually and updated as appropriate.

GUIDELINE AVAILABILITY

Electronic copies: Available Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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